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10/588,205	04/24/2008	Ulrich Schwaneberg	Q96421	6752

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EXAMINER	
KELLY, ROBERT M	
ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
08/08/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)
	10/588,205	SCHWANEBERG ET AL.
	Examiner	Art Unit
	ROBERT M. KELLY	1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)	
1) ☐ Notice of References Cited (PTO-892)	4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) ☐ Notice of Informal Patent Application
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.	6) ☐ Other: _____.

DETAILED ACTION

Applicant's response and amendment of 5/19/11 is entered.

Claim 4 is amended.

Claims 1-11 remain pending and are presently considered.

Election/Restriction

The Examiner rejoined all claims in the first office action on the merits in this case.

IDS

The IDS of 5/19/11 and references therein have been considered. The Examiner thanks applicant for proper recitations.

Claim Objections

In light of the amendment, the objection to Claim 4 for improper article citation is withdrawn.

Specification

In light of the amended abstract, the objection to the specification is withdrawn.

Drawings

In light of the amended drawings of 5/19/11, the objections to such are withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 5 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, for reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 5 is drawn to a generic enantioselective pore. The specification provides one example, Maltoporin (e.g., paragraph 44 of the publication), and states that by incorporating suitable amino acids, other transmembrane proteins or structures which were not previously enantioselective, can be made so, and that in the future, more enantioselective proteins may be found (e.g., Id.).

However, no example of a transmembrane protein or other trnasmembrane structure which can be modified by amino acids to become enantioselective is provided, and it is axiomatic that future-found enantioselective pores cannot be possessed.

Still further, the Examiner has found no more evidence of enantioselective pores utilized in vesicle membranes in the literature, and still further, *In re Alonso*, 88 USPQ.2d 1849 (Fed. Cir. 2008), makes clear that a single species does not provide sufficient written description for a genera, much less an absence of species.

Hence, given the only description of maltoporin, the Artisan would not have understood Applicant to have been in possession of the genera of enantioselective pores presently claimed.

Response to Argument - written description (enantioselective pores)

Applicant's response of 5/19/11 has been fully considered but is not found persuasive.

Applicant argues MPEP 2163, wherein it is stated that that evidence indicating ordinary artisan could not predict the operability of the invention would be a situtation where a single species may not constitute written description, and that "On the other hand, there may be situations where one species adequately supports a genus", quoting Rasmussen in the MPEP. Applicant then cites six articles to argue that the Artisan would understand from the disclosure that Applicant was indeed in possession of a protein with an enantioselective pore, and that maltoporin is representative of the genus, and that therefore, the rejection should be withdrawn (pp. 9-10).

Such is not persuasive. The quotes from the MPEP are certainly true, but are not applicable in this case. Also, in order to make the record clear, the Examiner meant that, when searching for art, he could not find enantioselective pores which are utilized in vesicle membranes, not that he was unaware of any other enantioselective pores. The rejection language has been changed to reflect such, hopefully clearer, terminology. Moreover, regardless of the MPEP, which is vague on which instances a single member of a genus may be used, and the quotes, which are taken from older case law than the present citation, the Examiner is supposed to uphold patent law, not MPEP guidelines. In recent training, the Examiner was specifically told by the Office that In re Alonso should be applied when a single species is divulged by Applicant and is applicable. No mention was made of instances where members of the genus are known in the Art, or how they are known in the Art, was provided to guide the Examiner. The training was taken to mean that a single species is not representative of a genus, period, given the teachings of In re Alonso. That said, the training is of course, not the law. So the following

analysis of the decision of In re Alonso to show how it is specifically applicable to Applicant's present situation. In Alonso, it was found that, because Applicant disclosed only species of monoclonal antibody which binds a neurofibrosarcoma, and because there exists substantial variability in the genus of neurofibrosarcomas in the structure required, the broad genus, encompassing many members, is not shown as possessed, given the showing of a single member of the genus (p. 1852). In Applicant's case, Applicant has shown a single enantioselective pore as being able to be utilized for the invention, and has failed to direct the Artisan to the structures in the Art which may also be utilized. Additionally, it was opined that a second method of determining possession is where the disclosure specifies "relevant identifying chargacteristics," such as "complete or partial structure, or other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of these characteristics" (p. 1854). However, Applicant has failed to any structure, and only provides the characteristic of being enantioselective. Further, it is true that each structure is specific to the molecule it must be enantioselective toward. Hence, the evidence is clear that many members must exist in this genera, as each molecule with an enantiomer must have a distinct pore to be utilized, and it is further true Applicant has provided no such structure required. Therefore, the rejection is proper.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 and 6-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-4 and 6-11 specifically encompass, or specifically require a pore which allows nucleic acids to traverse membrane. To wit, e.g., Claim 6 requires a positively charged oligomer for binding the substance, which may be polylysine (Claim 7), and the substance to be bound is a nucleic acid (Claim 9), and the substance released is a nucleic acid (Claim 11).

The specification only provides FhuA as a channel for such nucleic acids to traverse. Moreover, the Art provides no more channels which fit into liposomes. It is clear that these channels are not well known in the Art.

Finally, *In re Alonso*, 88 USPQ.2d 1849 (Fed. Cir. 2008), makes clear that a single species does not provide sufficient written description for a genera, much less an absence of species.

Therefore, the Artisan would not have understood Applicant to have been in possession of a generic nucleic acid pore, which is required to be present, or specifically encompassed, by the claims.

Response to Argument – written description, nucleic acid pores

Applicant's argument of 5/19/11 has been fully considered but is not found persuasive.

Applicant argues that the rejection is improper because the broader claims do not require the nucleic acid to be transportable by the pore (p. 12, paragraph 1).

Such is not persuasive. If the depending claims, as explained in the rejection, are drawn to a genus, the broader claims also specifically encompass such genus. To remove the rejection, however, the specific claims to such genus must be removed only.

Applicant argues the specification, on page 7 and page 8, to argue that the listing of a pore-forming unit having a beta barrel transmembrane structure, in particular "Rhodobacter capsulatus porin, Rhodopsudomonas blastica porin, Omp, SrcY, FepA, PhoE and, in particular for substances having a molecular weight <1000 Da, OmpF, LamB, OmpK36, and for substances having a molecular weight> 1000 Da FhuA, TOIC, maltoporin, and alpha-haemolysin", provides adequate written description for the pore unit of claim 1 (p. 12).

Such is not persuasive. The rejection is not for a pore unit, but for a pore unit which allows nucleic acids to traverse the membrane. Rhodobacter capsulatus porin is not taught in the art for nucleic acids, but for many small charged molecules. OmpF binds peptidoglycans, not nucleic acids. FhuA binds nucleic acids, but is the only member here which binds to nucleic acids with specificity. TOIC (A.K.A. mukA) is involved in chromosome partitioning. Given this, it appears to the Examiner that only FhuA is disclosed as a nucleic acid pore protein. Following similar analysis to that of the enantiomeric pore forming unit, ABOVE, the same lack of written description is found.

Applicant argues that Claims 9-11 do not require such pore-forming unit, and hence, the rejection is again improper for such (p. 13).

Such is not persuasive. Claims 9-11 require the substance which binds to be a nucleic acid. The specification describes the substances as passing through the pore-forming unit to bind. The independent claims separately provides for depending claim(s) which are to nucleic acid binding pores. Hence, these claims are not only specifically encompassing such pores, but also, from the description provided, specifically require such pores, due to the teachings in the specification of how the invention works.

Applicant argues pages 7-8 and 10 to argue that the pore-unit, having a beta barrel, for substances have a molecular weight over 1000 Da may be FhuA, that FhuA has a beta-barrel, and permits transport of phage DNA, that corresponding pore units to FhuA or beta-barrels allow not only small atoms and molecules but also larger molecules including DNA and RNA to pass into the interior of the vesicles according to the invention, provides sufficient description for more than FhuA (p. 14).

Such is not persuasive. The argument appears to be that the beta-barrel structure provides for passage of nucleic acids, thereby linking the structure to the function. However, the other porins cited in the same description to beta-barrels do not appear to be nucleic acid pores. Hence, for even these described embodiments, it is not the beta barrel itself which is required of the structure. Hence, sufficient structure required is again not provided for the function. Moreover, the argument citation itself appears to disagree with the analysis provided for the previous argument, in stating that the porins allow for the passage of the molecule, and specifically for the nucleic acid (Applicant's citation of page 10).

Applicant argues that the substances of FhuA, TOIC, maltoporin, and alpha-haemolysin, being listed as effecting larger substances of over 1000 Da, provides description for nucleic acids (p. 14, last paragraph).

Such is not persuasive. TOIC, as mentioned above, is for segregation of nucleic acids, not for passage of nucleic acids through a membrane, as is required for the invention. Maltoporin is a family of proteins which allow maltodextrins to cross the membrane in the Art, not nucleic acids. Alpha-haemolysin is a protein which is an exotoxin that allows lysis of proteins through forming a pore in the cell, and is not taught in the Art as specific to nucleic acids. Even in Applicant's teachings quoted, the porins cited are not taught as specific for

nucleic acids, but only as for the structure of having a beta-barrel and being a pore-forming unit. There is simply no possession of the genera which is for nucleic acid passage.

Applicant broadly states that the disclosure at pages 7, 8, 11-15, 28-30, and page 11 provides description for pore forming units capable of transferring substances over 1000 Da, including nucleic acids, and hence, possession is found (p. 15).

Such is not persuasive. This evidence is adequately reviewed by the specific recitations in the argument, which are answered above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 2003/106589 to Anderson; and WO 01/32146 to Meier, et al.

Anderson teaches nanopourous particles with a retained target (e.g., TITLE). Such particles may be utilized in chemical isolation or cleanup (p. 9, paragraph 2). The chemical is taught to diffuse within the pourous nanostructured liquid or liquid crystalline particle or material and is bound by the target (p. 9, paragraph 2). The target is substantially retained within the nanoporous particle (e.g., ABSTRACT). Hence, the chemical can bind to the target and be held within the nanoparticle and isolated from the bulk media (e.g., p. 11, last paragraph).

What Anderson does not teach is to utilize a vesicle containing a target molecule bound to the interior of the vesicle, in order to allow the medium inside the particle to be the same as

the bulk medium. What Anderson teaches is liquid crystalline mediums, which are naturally segregated from the bulk medium (e.g., pp. 12-13).

Meier teaches vesicles made of amphiphilic tri-block copolymers (e.g., ABSTRACT). Molecules, such as membrane proteins may be incorporated into the walls of the nanocapsules made (e.g., ABSTRACT). The nanocapsules may also contain a gating function protein, e.g., porins (e.g., p. 16, paragraph 4). Meier teaches at least one use for these vesicles includes removal of contaminants (e.g., p. 16, paragraph 7).

With the combination of teachings, the Artisan would be aware that a vesicle could be made similar to Meier, and containing an internally-linked ligand which binds to a target molecule, and containing pores large enough to diffuse a target molecule. The Artisan would be motivated to do so to product isolation or chromatography. Moreover, the Artisan would have a reasonable expectation of success, as the various components are utilized for art-recognized purposes.

With regard to Claim 2, it is noted that all substances bind reversibly through at least one of these interactions, and therefore, it is inherent that the target will bind the ligand through these interaction(s).

With regard to Claim 3, porins are transmembrane proteins.

With regard to Claim 4, ompF porins have pore diameters of 1.1nm at their narrowest constriction, but also contain areas of much larger diameters.

With regard to Claim 8, it is inherent in the methods of chromatography and removal of contaminants, that the substance to be isolated must come in contact with the vesicle.

Response to Argument – obviousness, Anderson and Meier

Applicant's argument of 5/19/11 has been fully considered but is not found persuasive.

Applicant cites guidelines for predictability when writing a rejection for obviousness, cites Anderson for describing a porous nanostructured material, in the cubic phase preferably, and preferably lyotropic (i.e., the crystal phase is formed in the presence of a solvent) and general descriptions that bilayers form in the presence of polar solvent with the alkanes inside and the polar groups outside the bilayer, and block copolymers form bicontinuous cubic phases with the same morphologies as found in lipid-water systems, further cites Anderson for surfactants being formed of polar lipids or block copolymers, and again for a surfactant being an amphiphile which modifies the interfacial physics of the aqueous phase and associating reversibly with each other and forming micelles, and finally a definition that an amphiphile is a compound containing both hydrophilic and lipophilic groups (pp. 17-18). Then Applicant looks to Meier to see that Meier teaches vesicles made of amphiphilic copolymers (e.g., ABA with A and B being alternately hydrophilic or hydrophobic (p. 18). Therefore, Applicant argues, the Artisan would not be motivated to combine Anderson's cubic phase liquid crystalline "cubosomes" with Meier's vesicles of amphiphilic copolymers because the result would be "entirely unpredictable, if not inoperable" (pp. 18-19, paragraph bridging).

Such is not persuasive. It's hard to discern a real argument here, as it seems to a shot-gun presentation of facts, and a general conclusion, but the Examiner believes Applicant's argument is that the ABA block copolymers of Meier, being single molecules with a structure similar to that of a liposome's bilayer (external groups being hydrophilic with a hydrophobic interior), but being a single molecule instead of a bilayer of hydrophobic groups arranged against each other with hydrophilic groups being exposed to the polar solvent, the structure is so distinct that it would not be predicted to work. Such is simply incorrect. If anything the whole of Meier is that the ABA copolymer with such a structure will work similar to a bilayer and hold such a protein.

If Applicant is arguing that proteins cannot be reasonably predicted to be held in the copolymers of Meier, such is not correct. Meier teaches placing similar channel proteins into such vesicles in Example 4.

Applicant cites Spicer (2005) Curr. Opin. Colloid Int. Sci., 10: 274-79, for stating that the liquid crystalline phase is more highly viscous than the bicontinuous cubic phase (albeit with "the same unique properties", as Applicant failed to emphasize in the same quotes), and argues that such means the Artisan would not expect"that Anderson's liquid crystalline particles could interact or solubilize the bilayer of meier's vesicles (p. 19).

Such is not persuasive. Applicant appears to understand the rejection wrong. Anderson teaches the overall organization of the internal binding entity, and channel, but the rejection then takes such and applies it to a vesicle instead of the bicontinuous phase.

Applicant continues to argue that the cubosome particles could not be placed into vesicles (pp. 20-23).

Such is not persuasive. The rejection is not to place the cubosomes into vesicles, but to modify Meier's vesciles in an analogous manner to achieve the same result as the cubosomes, but in the bulk medium, instead of segregated like the cubosomes are.

Maltporin

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5 and 8 remain rejected under 35 U.S.C. 103(a) as being unpatentable over WO 2003/106589 to Anderson; and WO 01/32146 to Meier, et al., as applied to claims 1-4 and 8 above, and further in view of Danelon, et al. (2003) Journal of Biological Chemistry, 278(37): 35542-51, for reasons of record.

As shown above, the base claims are obviated, but the use of an enantioselective channel is not.

However, Danelon teaches one such enantioselective channel, maltoporin, and its orientation in the membrane (e.g., ABSTRACT).

Hence, it would have been obvious to further modify the invention to utilize maltoporin as the pore. The Artisan would do so to isolate maltodextrins from bulk media in separations or chromatography. Moreover, the Artisan would have a reasonable expectation of success, as the various components are utilized for Art-recognized purposes.

Response to Argument – obvious, addition of Danelon

Applicant's argument of 5/19/11 has been fully considered but is not found persuasive.

Applicant argues that the references does not overcome the base deficiencies (pp. 22-23).

Such is persuasive. Applicant has interpreted the rejection incorrectly.

Nucleic Acid Isolation with polylysine

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 and 8 remain rejected under 35 U.S.C. 103(a) as being unpatentable over WO 2003/106589 to Anderson; and WO 01/32146 to Meier, et al., as applied to claims 1-4 and 8, above, and further in view of Locher, et al. (1998) Cell, 95: 771-78 and Cotton, et al. (2001) Current Protocols in Human Genetics, Chapter 12, Unit 12.3, Supplement 11, Wiley Online Library, 12.3.1-12.3.33, John Wiley & Sons, Inc, for reasons of record.

As shown above, the base references are obviated, however, the use of a nucleic acid pore is not, nor is the use of polylysine for the binding substance.

On the other hand, Locher teaches a modified FhuA channel which can be made to allow large DNAs to pass (p. 771), and Cotton teaches that polylysine can bind to DNA (p. 12.3.1).

Moreover, it is inherent in the separations that the substance (DNA) to be isolated from the medium must necessarily be contacted with the vesicle.

Further, Official Notice is given that it is well known to add salt to separate charge-bound molecules, including polylysine. Also, Official Notice is provided that shear stress is known for destroying vesicles.

Hence, it would be further obvious to modify the method to utilize the FhuA of Locher, and the polylysine of Cotton. The Artisan would do so to separate DNA from the medium and bind it within the vesicle. Moreover, the Artisan would have a reasonable expectation of success, as each of the parts are utilized for art-recognized purposes.

Response to Argument – obvious, addition of Locker and Cotton

Applicant's argument of 5/19/11 has been fully considered but is not found persuasive.

Applicant argues that the references does not overcome the base deficiencies (pp. 22-23).

Such is persuasive. Applicant has interpreted the rejection incorrectly.

Use of Liposome

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5 and 8 remain rejected under 35 U.S.C. 103(a) as being unpatentable over WO 2003/106589 to Anderson; and WO 01/32146 to Meier, et al., and Danelon, et al. (2003) Journal of Biological Chemistry, 278(37): 35542-51, as applied to claims 1-5 and 8 above, and further in view of U.S. Patent No. 6,958,160 to Keller, et al. and Hansen, et al. (December 2002) Journal of the American Society for Mass Spectrometry, 13(12): 1376-87, for reasons of record.

As shown above, the base claims are obviated, but the use of an enantioselective channel is not.

As shown above, the various references obviate the claims, but fail to teach the use of liposomes for use in the method as the vesicle.

On the other hand, liposomes are known in the Art, and utilized for containing and studying membrane-bound proteins, and for containing molecules for delivery. For Example, Keller teaches lipsomes for drug delivery, including nucleic acids (e.g., Claim 5) and Hansen, et al. (December 2002) Journal of the American Society for Mass Spectrometry, 13(12): 1376-87 teaches the use of liposomes to study transmembrane protein behavior of hydrophobic peptides.

From this, given the similar structure and known ability to incorporate proteins into the membranes of liposomes, it would be further obvious to utilize a liposome to perform the purifications/isolations. The Artisan would do so given their similar structure and ability to

separate the substances. Moreover, the Artisan would expect success, as the components are utilized for art-recognized purposes.

Response to Argument – obvious, addition of Keller and Hansen

Applicant's argument of 5/19/11 has been fully considered but is not found persuasive. Applicant argues that the references does not overcome the base deficiencies (pp. 22-23). Such is persuasive. Applicant has interpreted the rejection incorrectly.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 and 6-11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over WO 2003/106589 to Anderson; and WO 01/32146 to Meier, et al., Locher, et al. (1998) Cell, 95: 771-78 and Cotton, et al. (2001) Current Protocols in Human Genetics, Chapter 12, Unit 12.3, Supplement 11, Wiley Online Library, 12.3.1-12.3.33, John Wiley & Sons, Inc., as applied to claims 1-4 and 6-11, above, and further in view of U.S. Patent No. 6,958,160 to Keller, et al. and Hansen, et al. (December 2002) Journal of the American Society for Mass Spectrometry, 13(12): 1376-87, for reasons of record.

As shown above, the various references obviate the claims, but fail to teach the use of liposomes for use in the method as the vessicle.

On the other hand, liposomes are known in the Art, and utilized for containing and studying membrane-bound proteins, and for containing molecules for delivery. For Example,

Keller teaches lipsomes for drug delivery, including nucleic acids (e.g., Claim 5) and Hansen, et al. (December 2002) Journal of the American Society for Mass Spectrometry, 13(12): 1376-87 teaches the use of liposomes to study transmembrane protein behavior of hydrophobic peptides.

From this, given the similar structure and known ability to incorporate proteins into the membranes of liposomes, it would be further obvious to utilize a liposome to perform the purifications/isolations. The Artisan would do so given their similar structure and ability to separate the substances. Moreover, the Artisan would expect success, as the components are utilized for art-recognized purposes.

Response to Argument – obvious, addition of several references

Applicant's argument of 5/19/11 has been fully considered but is not found persuasive. Applicant argues that the references does not overcome the base deficiencies (pp. 22-23). Such is persuasive. Applicant has interpreted the rejection incorrectly.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT M. KELLY whose telephone number is (571)272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert M Kelly/
Primary Examiner, Art Unit 1633